UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,732	10/17/2003	Stephen Orlicky	14096.34USU1	6533

23552 7590 03/13/2006

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
TALAVERA, MIGUEL A	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,732	ORLICKY ET AL.	
	Examiner	Art Unit	
	Miguel A. Talavera	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. Claims 1-25 are pending in the application.

3. For the purpose of restricting the claims, the examiner has interpreted claim 24 as a method of using a modulator of a binding pocket of claim 1 in the manufacture of a medicament to treat and/or prevent a disease in a mammal. If this interpretation is incorrect, applicant is requested to clarify the record.

Information Disclosure Statement

4. The Examiner can find no information disclosure statement (IDS) filed in the instant application. The listing of references in the specification (pp. 258-262) is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and M.P.E.P. § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references are cited by the examiner on form PTO-892, they have not been considered.

Compliance with the Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequence set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990) and 1114 OG 29 (May 15, 1990).

a) The structural coordinates in Tables 6 teach an amino acid sequence(s) since a particular amino acid is assigned to a linear sequence(s) in a particular order. As such, the amino acid sequence(s) disclosed within the atomic coordinates must comply with the sequence rules. Labeling using a SEQ ID NO must be inserted into the brief description of the drawings or into the Figure directly.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

b) Several nucleotide sequences are taught in Table 7. When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence

identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. See M.P.E.P. § 2422.02.

Restriction

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims1-8 and 12-18, drawn to an isolated binding pocket of a SFC complex or a component thereof, and crystals comprising said binding pocket, classified in class 435, subclass 183.

II. Claims 9-11, drawn to a model of a binding pocket of a SCF complex, classified in class 702, subclass 27.

III. Claim 19, drawn to a computer readable medium, classified in class 702, subclass 19.

IV. Claim 20, drawn to a method of determining the secondary and/or tertiary structure of a polypeptide, classified in class 703, subclass 11.

V. Claim 21, drawn to a method for screening a ligand using a protein crystal, classified in class 702, subclass 27.

VI. Claims 22 and 24, drawn to a method of conducting drug discovery and producing a medicament using the crystals of Group I, classified in class 703, subclass 2.

VII. Claim 23, drawn to a method for regulating an SCF complex by changing a structure of binding pocket, classified in class 702, subclass 27.

VIII. Claim 25, drawn to a pharmaceutical composition comprising a ligand or modulator of a binding pocket, classified in class 514, subclass 789.

The polypeptides and crystals of Group I, the model of a binding pocket of Group II, the computer readable medium of Group III, and the pharmaceutical composition of Group VIII are unrelated inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are patentably distinct products because they are chemically different and not disclosed as capable of use together. Initially, the polypeptides of Group I are not disclosed as useable with the molecular model of Group II, the computer-readable medium of Group III, and the pharmaceutical composition of Group VIII. Secondly, the points in space comprising a molecular model of Group II are not disclosed as useable together with the computer readable medium or the pharmaceutical composition. Finally, the computer readable medium has multiple utilities (i.e., ranging from word processing and record keeping to numerical and statistical analysis) and is not disclosed as useable together with the pharmaceutical composition of Group VIII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups I-III and Group VIII have been properly restricted as being distinct and presenting a search burden on the Office if they were to be searched together.

The methods of Group IV-VII are related because the methods of all of these Groups include a common method step for the use of the crystals of Group I. Although the methods of these Groups are related, they are distinct inventions because they have different method steps and yield different results. For example, the products of Groups IV are secondary and/or tertiary

structure of polypeptides, the products of Group V are ligands of SRC complex, the products of Group VI are structurally modified variants SCF complex and the product of Group VII is a medicament and/or pharmaceutical preparations. Thus, Groups IV, V, VI and VII are distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups IV, V, VI, and VII have been properly restricted as being distinct and presenting a search burden on the Office if they were to be search together.

The polypeptides and crystal forms of Group I are related to the methods of Groups IV-VII as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, polypeptides of Groups I can be used for raising antibodies. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Group I and Groups IV-VII have been properly restricted as being patentably distinct and presenting a search burden on the Office if they were to be searched together.

The points in space comprising a molecular model of Group II and the computer readable medium of Group III are unrelated to the methods of Groups IV-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups IV-VII, cannot be use to make the points in space

comprising a molecular model Group II nor the computer readable medium of Group III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups II and III and Groups IV-VII have been properly restricted as being patentably distinct and presenting a search burden on the Office if they were to be searched together.

The pharmaceutical composition of Group VIII is unrelated to the methods of Groups IV, V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups IV, V and VII, cannot be use to make pharmaceutical composition of Group VIII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups VIII and Groups IV, V and VII have been properly restricted as being patentably distinct and presenting a search burden on the Office if they were to be searched together.

The methods of Group VI and the pharmaceutical composition of Group VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the pharmaceutical composition can be synthesized *de novo*, i.e., without structural guidance of the target structure. Because these inventions are distinct for the reasons given above and have acquired a separate

status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Group VI and Group VIII have been properly restricted as being patentably distinct and presenting a search burden on the Office if they were to be searched together.

Notice of Possible Rejoinder

1. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim

will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Election

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1 .48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Miguel A. Talavera whose telephone number is (571)272-3354. The examiner can normally be reached on M-F, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on (571)272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER

Miguel A. Talavera, Ph.D.
March 02, 2006